European Medicines Agency

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PUBLIC STATEMENT ON

TENECTEPLASE BOEHRINGER INGELHEIM PHARMA GmbH & Co. KG (tenecteplase)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 23 February 2001, the European Commission granted a marketing authorisation for Tenecteplase Boehringer Ingelheim Pharma KG (tenecteplase) for the whole European Union to Boehringer Ingelheim International GmbH. Tenecteplase Boehringer Ingelheim Pharma KG is an antithrombotic agent containing tenecteplase, a recombinant fibrin-specific plasminogen activator that binds to the fibrin component of the thrombus (blood clot) and selectively converts thrombus-bound plasminogen to plasmin, which degrades the fibrin matrix of the thrombus. Tenecteplase Boehringer Ingelheim Pharma KG has been developed for thrombolytic treatment of suspected myocardial infarction (MI) with persistent ST elevation or recent left Bundle Branch Block within 6 hours after the onset of acute MI symptoms.

Tenecteplase Boehringer Ingelheim Pharma KG is not marketed anywhere in the EU. On 28 June 2005, Boehringer Ingelheim International GmbH notified the European Commission of its decision to withdraw the Community Marketing Authorisation for Tenecteplase Boehringer Ingelheim Pharma KG for commercial reasons. There is still one Community Marketing Authorisation valid throughout the European Union for medicinal products containing tenecteplase, namely Metalyse. In addition, alternative treatments are available in Europe for this indication.

On 9 August 2005, the European Commission issued a decision to withdraw the Marketing Authorisation for Tenecteplase Boehringer Ingelheim Pharma KG. Consequently, the European Public Assessment Report for Tenecteplase Boehringer Ingelheim Pharma KG has been removed from the EMEA website.

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